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MCDONNELL BOEHNEN HULBERT @ BERGHOFF LLP 300 SOUTH WACKER DRIVE

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SUITE 3100

DEC 1 5 2009

CHICAGO IL 60606

OFFICE OF PETITIONS

In re Patent No. 7,576,074 : DECISION ON REQUEST FOR

Rice et al. RECONSIDERATION OF

Issue Date: August 18, 2009 : PATENT TERM ADJUSTMENT

Application No. 10/522,004 : AND NOTICE OF INTENT TO ISSUE

: CERTIFICATE OF CORRECTION Filed: April 11, 2005

Docket No.02-420-H

This is in response to the PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT FILED UNDER 37 C.F.R § 1.705(d), filed August 21, 2009. Patentees request that the determination of patent term adjustment for the above-identified patent be corrected from four hundred seventy-five (475) days to one thousand twenty-seven (1,027) days.

The request for reconsideration of the patent term adjustment indicated in the patent is GRANTED to the extent indicated herein.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond. No extensions of time will be granted under 37 CFR 1.136.

The patent term adjustment indicated on the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of 560 days.

On August 18, 2009, the above-identified application matured into U.S. Patent No. 7,576,074. The patent issued with a revised patent term adjustment of 475 days. The present request for reconsideration of patent term adjustment was timely filed on

August 21, 2009, within two months of the issue date of the patent. See 37 CFR 1.705(d).

Patentees request recalculation of the patent term adjustment based on the decision in <a href="Wyeth v. Dudas">Wyeth v. Dudas</a>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees aver that the correct number of days of Patent Term Adjustment is 1,027 days under the court's interpretation of the overlap provision as set forth in <a href="Wyeth v. Dudas">Wyeth v. Dudas</a>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to <a href="Wyeth">Wyeth</a>, a PTO delay under 35 U.S.C. 154(b)(1)(A) overlaps with a delay under 35 U.S.C. 154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the total non-overlapping PTO delay under 35 U.S.C. 154(b)(1)(A) (465 days) and 35 U.S.C. 154(b)(1)(B) (581 days) is 1,047 days as these periods do not occur on the same day. Further, given the applicant delay of 19 days, patentees assert entitlement to 1,027 (1,047 - 19) days of patent term adjustment.

Patentees also assert that Office used an incorrect date in calculating the over three delay under 35 U.S.C. 154(b)(1)(B) and specifically state:

The B delay is the number of days an application was pending beyond 3 years...The B delay period begins the day after 3 years after the national stage commenced, which is January 16, 2008. So, the B delay is the period from January 16, 2008, to the issue date, August 18, 2009, or 581 days.

In the Office's PTA calculation, it appears the B delay was calculated based on the 35 USC § 371(c) date rather than the 35 USC § 371(b) date. The Patent Office calculated the B delay starting from April 12, 2008 (3 years plus one day after the § 371(c) date) and ending August 18, 2009 (the issue date, thus arriving at 494 days rather than 581 days.

Excerpt taken from "Petition for Reconsideration of Patent Term Adjustment Filed Under 37 CFR § 1.705(d)", filed August 21, 2009, p. 2.

At the outset, a review of the record indicates that neither the Office, nor patentees, used the 35 U.S.C. 371(b) national stage commencement date of January 17, 2005, in calculating the period of adjustment under 37 CFR 1.703(b). While is noted that the date that was thirty months from the priority date of July 15, 2002, was January 15, 2005, it is also noted that

January 15, 2005, was a Saturday. Relative to applications filed under 37 CFR 371(b), when the date that is thirty months from the priority date-which would ordinarily be the date the national stage commenced under 35 U.S.C. 371(b) -- falls on a weekend, the date of commencement shifts to the next business In this instance, the next business day was Monday January 17, 2005. Accordingly, the date the national stage commenced under 35 U.S.C. 371(b) is January 17, 2005. stated in 37 CFR 1.703(b), the period of adjustment under § 1.702(b) is the number of days in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) in an international application and ending on the day before the filing of the request for continued examination (not including any other periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)).

Pursuant to 37 CFR 1.703(b), the period of adjustment under 37 CFR 1.702(b)<sup>1</sup> is 579 days, counting the number of days beginning on the day after the date that is three years after the date on which the national stage commenced under 35 U.S.C. 371(b), January 18, 2008, and ending on August 18, 2009, the day the patent issued.

As to patentees' interpretation of the period of overlap, the Office finds it inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A). 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Pursuant to 35 U.S.C. 154(b)(1)(B), 37 CFR 1.702(b) provides, in pertinent part, that:

Failure to issue a patent within three years of the actual filing date of the application. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application[.]

As explained in Explanation of 37 CFR  $1.703(f)^2$  and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154 (b) (2) (A), 69 Fed. Reg. 34283 (June 21, 2004).

Further, as stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35  $U.S.C.\ 154(b)(2)(A)$ , the Office has consistently taken the position that if an application is entitled to an adjustment under

<sup>&</sup>lt;sup>2</sup> Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding 37 CFR 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office, January 17, 2005, the date of commenced under 35 U.S.C 371(b), to August 18, 2009, the day the patent issued.

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1) and  $(a)(2)^3$ , 466 days of patent term adjustment were accorded during the pendency of the application for Office delay prior to the issuance of the patent. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR  $1.702(b)^4$ , 579 days of patent term adjustment accrued for Office issuance of the patent more than three years after the date the national stage commenced under 35 U.S.C. 371(b).

The 579 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 466 days of patent term adjustment under 37 CFR 1.702(a)(1) and (a)(2). Entry of both the 579 days and the 466 days is neither permitted nor warranted. 579 days is the actual number of days issuance of the patent was delayed. Accordingly, the period adjustment of 28 days will be removed and the additional period of adjustment of 113 days will be entered for the Office for failing to issue the patent within three years.

<sup>&</sup>lt;sup>3</sup> A restriction requirement was mailed on September 19, 2007, fourteen months and 465 days after the date of completion of all 35 U.S.C. 371 requirements on April 11, 2005. On October 28, 2008, a final Office action was mailed, 4 months and 1 day after a response was filed on June 27, 2008.

<sup>&</sup>lt;sup>4</sup> The application was pending three years and 579 days.

In view thereof, the patent term adjustment indicated on the patent should be 560 days.

The Office acknowledges the submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by 560 days.

Telephone inquiries regarding this matter should be directed to Kenya A. McLaughlin, Petitions Attorney, at (571) 272-3222.

Christina Tartera Donnell Senior Petitions Attorney Office of Petitions

Enclosure: Copy of DRAFT Certificate of Correction

## **DRAFT COPY**

## UNITED STATES PATENT AND TRADEMARK OFFICE

## **CERTIFICATE OF CORRECTION**

**PATENT** 

: 7,576,074 B2

DATED

: Aug. 18, 2009

INVENTOR(S): Rice, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[\*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (475) days

Delete the phrase "by 475 days" and insert - by 560 days--